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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 07-4284 (SRC) (MAS) Civil Action No. 08-4059 (SRC) (MAS) (consolidated with 07-4284 for all purposes) **PLAINTIFF HOFFMANN-LA ROCHE INC.'S INITIAL CLAIM CONSTRUCTION BRIEF**

HOFFMANN-LA ROCHE INC., Plaintiff, v. GATE PHARMACEUTICALS (a Division of Teva Pharmaceuticals USA, Inc.), TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 07-4285 (SRC) (MAS) Civil Action No. 08-4058 (SRC) (MAS) (consolidated with 07-4285 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-4417 (SRC) (MAS) Civil Action No. 08-3065 (SRC) (MAS) Civil Action No. 08-4053 (SRC) (MAS) (consolidated with 07-4417 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 07-4516 (SRC) (MAS) Civil Action No. 08-3607 (SRC) (MAS) Civil Action No. 08-4055 (SRC) (MAS) (consolidated with 07-4516 for all purposes)

HOFFMANN-LA ROCHE INC., Plaintiff, v. COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC., Defendants.	Civil Action No. 07-4539 (SRC) (MAS) Civil Action No. 07-4540 (SRC) (MAS) Civil Action No. 08-4054 (SRC) (MAS) (consolidated with 07-4539 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE, ORCHID PHARMACEUTICALS INC., and ORGENUS PHARMA INC., Defendants.	Civil Action No. 07-4582 (SRC) (MAS) Civil Action No. 08-4051 (SRC) (MAS) (consolidated with 07-4582 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. GENPHARM INC. and GENPHARM, L.P., Defendants.	Civil Action No. 07-4661 (SRC) (MAS) Civil Action No. 08-4052 (SRC) (MAS) (consolidated with 07-4661 for all purposes)

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Plaintiff Hoffmann-La Roche Inc. ("Roche") submits this Initial Claim Construction Brief. Roche respectfully requests a claim construction to resolve disputes over the meanings of five claim terms used in U.S. Patent No. 4,927,814 ("the '814 patent") and eight claim terms that are used in U.S. Patent Nos. 7,192,938 ("the '938 patent") and 7,410,957 ("the '957 patent"). Roche relies on the certified copies of the three patents in suit and their respective prosecution histories contained in the Joint Appendix also submitted to the Court. (cited as "JOINT APP - __"); and the Declaration of Mark E. Waddell in Support of Plaintiff Hoffmann-La Roche Inc.'s Initial Claim Construction Brief ("Waddell Decl.") attaching, *inter alia*, the expert reports of James J. Benedict, Ph.D., John P. Bilezikian, M.D. and Charles H. Chesnut III, M.D[1].

[1] Opening Expert Report of James J. Benedict, Ph.D., dated July 28, 2009 ("Benedict Rpt., Waddell, Decl., Exh. A"); Opening Expert Report of John P. Bilezikian, M.D., dated July 28, 2009 ("Bilezikian Rpt., Waddell, Decl., Exh. B"); Opening Expert Report of Charles H. Chesnut, III, M.D. Regarding Infringement of Gall U.S. Patent No. 4,927,814, dated July 27, 2009 ("Chesnut '814 Rpt., Waddell, Decl., Exh. C"); Opening Expert Report of Charles H. Chesnut, III, M.D. Regarding Infringement of Bauss U.S. Patent No. 7,192,938 and Bauss U.S. Patent No. 7,410,957, dated July 27, 2009 ("Chesnut '938/ '957 Rpt., Waddell, Decl, Exh. D").

I. BACKGROUND

These cases arise out of actions for patent infringement concerning proposed generic copies of Roche's highly successful osteoporosis drug Boniva®. The FDA has approved Boniva® for treatment or prevention of postmenopausal osteoporosis in postmenopausal women. (Bilezikian Rpt, Waddell, Decl., Exh. B, ¶¶ 24-25). Defendants are generic drug companies who have filed Abbreviated New Drug Applications ("ANDAs") seeking approval from the United States Food and Drug Administration ("FDA") to engage in the manufacture, use, and sale of generic versions of Boniva® prior to the expiration of Roche's patents.

The '814 patent was issued in 1990 and covers the active ingredient in Boniva® - ibandronate sodium. (JOINT APP-0002; Benedict Rpt., Waddell, Decl., Exh. A, ¶ 74; Bilezikian Rpt, Waddell, Decl., Exh. B, ¶ 25). The '814 patent will expire on March 17, 2012. Apotex and Cobalt are the only Defendants in these actions who challenged the '814 patent and seek FDA approval prior to its expiration in 2012[2].

The asserted claims in the '938 patent cover the treatment or inhibition of osteoporosis by once-monthly administration of a pharmaceutically acceptable salt of a bisphosphonic acid, such as ibandronate sodium (the active ingredient in

[2] There also is a statutory stay of FDA approval of all the Defendants ANDAs which expires November 16, 2010. But, Apotex and Cobalt are the only Defendants who might theoretically be able to launch at risk after November 16, 2010 (absent entry herein of either a final judgment or preliminary injunction).

Boniva®). (Bilezikian Rpt, Waddell, Decl., Exh. B, ¶¶ 41-53). The '938 patent was issued in 2007 and will expire on May 6, 2023. (JOINT APP-0424). All Defendants seek FDA approval prior to expiration of the '938 patent in 2023.

The '957 patent covers the treatment of osteoporosis by once-monthly administration of oral tablets containing ibandronate sodium. (Bilezikian Rpt, Waddell, Decl., Exh. B, ¶¶ 54-60). The '957 patent was issued in 2008 and will expire along with the '938 patent on May 6, 2023. (JOINT APP-1314). All Defendants seek FDA approval prior to expiration of the '957 patent in 2023.

II. THE CLAIM TERMS IN DISPUTE

Notwithstanding that these cases have been pending since 2007, as late as September 18, 2009, Defendants informed the Court that they had difficulty agreeing on the claim terms in dispute even among themselves. (Waddell Decl., Exh. L, p. 2). Based on multiple meet and confers with Defendants, Roche believes that disputes have crystallized over only a limited number of terms and will brief these here.

Roche asked Defendants whether any additional terms should be briefed. See e-mails dated September 23, 2009 (Waddell Decl., Exh. E), September 24, 2009 (Waddell Decl., Exh. F), and again on October 1, 2009 (See, e.g., Oct 1, 2009 e-mail in Waddell Decl., Exhs. I). The Defendants responded late on October 2, 2009 – just two business days before this brief was due. (Waddell Decl., Exhs. I

and J). Roche herein only briefs claim terms that were explicitly identified by Defendants on October 2, 2009. If Defendants brief or later dispute any additional terms, Roche will seek leave to supplement its opening brief.

A. Disputed Claim Terms in the '814 Patent

Defendants Apotex and Cobalt stated that they would be briefing the following terms in the '814 patent: "1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-disphosphonic acid"; "physiologically active salt"; "administering … 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid"; "pharmaceutical composition… containing … in a pharmaceutically acceptable carrier … at least one compound designated ... 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid"; and "calcium metabolism disturbance or disease." (E-mail, T. Ragahavan to M. Waddell, Oct. 2, 2009, Waddell Decl., Exh.I).

Claims 4, 8, and 12 of the '814 patent are being asserted in these actions and the disputed terms are highlighted below.

Claim 4 of the '814 patent reads[3]:

> 4. The diphosphonate compound of claim 1 designated **1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid and the physiologically active salt thereof.**

[3] ('814 Patent, Col. 13, ll. 36-39, JOINT APP-0009)(Emphasis supplied).

Claim 8 of the '814 patent reads[4]:

> 8. A method for the treatment or prophylaxis of **calcium metabolism disturbance or disease** comprising **administering** a pharmaceutically effective amount of at least one of the compounds designated 1-hydroxy-3-(N-methyl-N-nonylamino)-propane-1,1-diphosphonic acid, **1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid** and 1-hydroxy-3-(N-isobutyl-N-methylamino)-propane-1,1-diphosphonic acid.

Claim 12 of the '814 patent reads[5]:

> 12. **A pharmaceutical composition** for the treatment or prophylaxis of calcium metabolism disturbance or disease **containing** an effective amount in a pharmaceutically acceptable carrier of at least one compound designated 1-hydroxy-3-(N-methyl-N-nonylamino)-propane-1,1-diphosphonic acid, **1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid**, and 1-hydroxy-3-(N-isobutyl-N-methylamino)-propane-1,1-diphosphonic acid.

B. Disputed Claim Terms in the '938 Patent

Defendants stated that they would be briefing the following claim terms in the '938 patent claims. Defendants' e-mail stated:

> The terms Defendants (other than Cobalt) believe to be in dispute at the present time, and which we are planning on briefing at the present time are as follows:
>
> 1. "commencing treatment"

[4] ('814 Patent, Col. 14, ll. 11-18, JOINT APP-0009)(Emphasis supplied).

[5] ('814 Patent, Col. 14, ll. 32-41, JOINT APP-0009)(Emphasis supplied).

2. "orally administering to a subject in need of such treatment"

3. "a first dose"

4. "on a single day"

5. "continuing said treatment"

6. "once monthly"

7. "consisting of"

We don't believe that there are any additional terms from the '957 patent that need to be briefed.

(L. Walsh 5:22 PM e-mail, Oct. 2, 2009, Waddell Decl., Exh. J).

Roche was further advised that Defendant Cobalt "may be joining in some of the arguments made by the other Defendants, but also has some of its own issues, which perhaps some but not all of the other defendants might join, as well as having some issues that might be different from the other defendants." (L. Walsh 7:10 PM e-mail, Oct. 2, 2009, Exh. J). Cobalt did not provide a separate response. Therefore, Roche must presume (but still does not know) whether Cobalt is planning to brief any additional terms. If Cobalt briefs any additional claim terms, Roche may need to seek leave to supplement this opening brief.

The disputed terms appear in independent claims 1 and 16 of the '938 patent[6] (the disputed terms are highlighted in the quoted text).

[6] Roche is only asserting certain dependent claims in the '938 patent. Dependent claims 11 and 12 narrow the scope of claim 1 by specifying the dose and the use of a solid pharmaceutical composition. Dependent claims 26 and 27

Claim 1 of the '938 patent reads[7]:

> 1. A method for treating or inhibiting osteoporosis comprising **commencing treatment by orally administering to a subject in need of such treatment a first dose, on a single day**, of a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 100 mg to about 150 mg of said bisphosphonic acid and **continuing said treatment by orally administering, once monthly on a single day**, a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to from about 100 mg to about 150 mg of bisphosphonic acid.

Claim 16 of the '938 patent reads[8]:

> 16. A method for treating or inhibiting osteoporosis **consisting of orally administering to a subject in need of such treatment once monthly**, a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 100 mg to about 150 mg of said bisphosphonic acid.

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similarly narrow the scope of claim 16. None of the terms that are added in the asserted dependent claims has a disputed meaning.

[7] ('938 Patent, Col. 7, ll. 23-35, JOINT APP-0429)(Emphasis supplied).

[8] ('938 Patent, Col. 8, ll. 12-17, JOINT APP-0429)(Emphasis supplied).

C. Disputed Claim Terms in the '957 Patent

As noted above, Defendants do not intend to brief any terms of the '957 patent claims that are not in common with the '938 patent claims[9]. The disputed terms appear in independent claims 1 and 6 of the '957 patent (the disputed terms are highlighted in the quoted text).

Claim 1 of the '957 patent reads[10]:

> 1. A method for treating osteoporosis comprising **commencing treatment by orally administering to a subject in need of such treatment, on a single day, a first dose** in the form of a tablet, wherein said tablet comprises an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid and **continuing said treatment by orally administering, once monthly on a single day**, a tablet an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

Claim 6 of the '957 patent. Claim 6 of the '957 patent reads[11]:

> 6. A method for treating osteoporosis **consisting of orally administering to a subject in need of such treatment once monthly on a single day**, a tablet comprising an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

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[9] Defendants raised one potential new issue regarding the preamble of claims 1 and 6 in the '957 patent ("A method for treating osteoporosis") to which Roche responded on October 5, 2009. (See e-mails in Waddell Decl. Exh. K). Defendants have not responded whether this term should be briefed.

[10] ('957 Patent, Col. 7, ll. 17-26, JOINT APP-1320)(Emphasis supplied)

[11] ('957 Patent, Col. 7, ll. 37-42, JOINT APP-1320)(Emphasis supplied).

III. LEGAL STANDARD

Claim construction is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd., 517 U.S. 370 (1996). In general, the claim terms are given their ordinary and accustomed meaning to one of skill in the art. *Johnson Worldwide Assocs., Inc. v. Zebco Corp*., 175 F.3d 985, 988-90 (Fed. Cir. 1999). Claim construction, therefore, always begins and ends with the words of the claim. *Interactive Gift Express, Inc. v. Compuserve, Inc*., 256 F.3d 1323, 1331 (Fed. Cir. 2001). The claims, however, are not construed in a vacuum. *Toro Co. v. White Consolidated Indus., Inc*., 199 F.3d 1295, 1301 (Fed. Cir. 1999) ("The claim word 'including' is not construed in a lexicographic vacuum, but in the context of the specification and drawings").

Rather, it is well settled that the claims are construed in light of the specification and drawings and that it is the patentee's use of the terms in the patent, as understood by the skilled art worker, which controls. See *Phillips v. AWH Corp*., 415 F.3d 1303, 1314-16 (Fed. Cir. 2005) (en banc) (holding that a court should focus at the outset on how the patentee used the claim term in the claims, specification, and prosecution history); *Network, L.L.C. v. Centraal Corp*., 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose.")

Importantly, claim construction does not occur in a vacuum, but rather is considered in light of the Defendants' products and methods of treatment that are accused of infringement:

> Without knowledge of the accused products, this court cannot assess the accuracy of the infringement judgment under review and lacks a proper context for an accurate claim construction. "While a trial court should certainly not prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction."

Lava Trading, Inc. v. Sonic Trading Management, LLC, 445 F.3d 1348, 1350 (Fed. Cir. 2006) (quoting *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322 (Fed.Cir.2006)) (other citations omitted); and see *Jang v. Boston Sci. Corp.*, 532 F.3d 1330, 1337 (Fed. Cir. 2008) ("We have previously emphasized the importance of the context provided by an analysis of the accused device when ruling on claim construction and the problems presented by construing claims in the absence of such context".). This is necessary so that the Court is not merely providing an advisory opinion. See *Lava Trading*, at 1350 ("Without the vital contextual knowledge of the accused products or processes," the court's decision "takes on the attributes of something akin to an advisory opinion on the scope of the [] patent.").

In construing the claims, the Court may also look to the prosecution history. *Markman*, 52 F.3d at 967. This is because: "[d]uring prosecution, a patent applicant may consistently and clearly use a term in a manner either more or less expansive than it is used in the relevant art, thereby expanding or limiting the scope of the term in the context of the patent claims." *Sorenson v. International Trade Commission*, 427 F. 3d 1375, 1378 (Fed. Cir. 2005). The Federal Circuit has emphasized, however, that: "in order to disavow claim scope, a patent applicant must clearly and unambiguously express surrender of subject matter during prosecution." Id.; *see also Omega Engineering, Inc. v. Raytek Corp*., 334 F. 3d 1314, 1324 (Fed. Cir. 2003) ("We have, however, declined to apply the doctrine of prosecution disclaimer where the alleged disavowal of claim scope is ambiguous").

"The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation…[t]hat starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art." *Phillips*, 415 F.3d at 1312-1313; s*ee also Verve, LLC v. Crane Cams, Inc*., 311 F.3d 1116, 1119 (Fed. Cir. 2002) (patent documents are meant to be "a concise statement for persons in the field").

A court also may consider certain forms of extrinsic evidence to aid in determining the "true meaning of language employed" in the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d at 980-81. However, extrinsic evidence, such as expert testimony, cannot be used to vary or contradict the intrinsic evidence. *Phillips v. AWH Corp*., 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc) ("conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history'").

While claim limitations should be construed in light of the specification and prosecution history, it is legal error to import into the claim limitations that are not there. The Federal Circuit has repeatedly recognized that there is a difference between construing a term appearing in a claim, and adding a limitation that is not there in the first place. The former is permissible; the latter is not. As the Federal Circuit has explained, "[w]hen it comes to the question of which should control, an erroneous remark by an attorney in the course of prosecution of an application or the claims of the patent as finally worded and issued by the Patent and Trademark Office as an official grant, we think the law allows for no choice. The claims themselves control." *Intervet Am., Inc. v. Kee-Vet Labs., Inc*., 887 F.2d 1050, 1054 (Fed. Cir. 1989); *see, also*, *Interactive Gift Express*, 256 F.3d at 1331-32 ("in

looking to the specification to construe claim terms, care must be taken to avoid reading limitations appearing in the specification … into [the] claims") (citations omitted); *Burke, Inc. v. Bruno Indep. Living Aids, Inc*., 183 F.3d 1334, 1340 (Fed. Cir. 1999) ("Consistent with the principle that the patented invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history."); *Laitram Corp. v. NEC Corp*., 163 F.3d 1342, 1348 (Fed. Cir. 1998) ("interpreting what is meant by a word and a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper'"); and see also *Bayer AG v. Biovail Corp*., 279 F.3d 1340, 1348 (Fed. Cir. 2002).

IV. DISCUSSION

A. Technical Background

A brief discussion of the technical background underlying the infringement issues in these cases is presented to assist the Court. As mentioned, Defendants have filed ANDAs seeking FDA approval to engage in the manufacture, use, and sale of generic versions of Boniva® prior to the expiration of Roche's patents. The FDA has approved Boniva® for treatment or prevention of osteoporosis in postmenopausal women. (Bilezikian Rpt, Waddell, Decl., Exh. B, ¶¶ 24-25).

Roche's expert, John P. Bilezikian, M.D. is board certified in internal medicine and in endocrinology and metabolism and has extensive experience in

osteoporosis research. (Bilezikian Rpt., Waddell Decl., Exh. B, attached CV at p. 21). Dr. Bilezikian explains in paragraphs 32-33 of his report that:

> Osteoporosis is a common disorder of bone metabolism characterized by reduced bone density and bone quality (based on factors such as bone size, bone shape, microarchitecture, mineralization, and matrix quality) leading to a reduction in bone strength and increased susceptibility to fractures…. This definition has replaced older definitions that were based primarily on a reduction in bone density. Osteoporosis results from an imbalance in the bone remodeling process that develops, in part, as a component of the aging process. Throughout a person's life, his or her bones undergo a continuous process of resorption and formation brought about by the complex interaction of different types of cells, called osteoclasts and osteoblasts. This process, called bone remodeling, is the means by which older bone is replaced by younger, more resilient bone. It is important that bone remodeling be balanced, that is, the amount of bone removed (i.e., resorbed) is balanced by the amount of bone formed.

The active ingredient in Boniva® is ibandronate sodium. (Bilezikian Rpt, Waddell, Decl., Exh. B, ¶ 25). Ibandronate Sodium belongs to a class of drugs known as "bisphosphonates" or "diphosphonates". Roche's expert, James J. Benedict Ph.D., an experienced medicinal chemist in the bisphosphonate field, provides an extensive review of the chemistry and chemical nomenclature used in this field of chemistry in his expert report. (Benedict Rpt., Waddell Decl., Exh. A, ¶¶ 3-15, ¶¶ 28-61).

B. The '814 Patent Terms

Claims are construed as they would be understood by the person skilled in the art. *Phillips v. AWH Corp* at 1314-16. As discussed by Dr. Benedict, the '814 patent pertains to geminal diphosphonates ("bisphosphonates"), compositions containing them, processes for their preparation, and methods of treatment employing them. These bisphoshonates include the compound ibandronic acid as well as its sodium salt ibandronate sodium. (Benedict Rpt., Waddell Decl., Exh. A, ¶¶ 64-68). According to Dr. Benedict:

> With regard to the chemical compounds ibandronic acid and ibandronate sodium covered by claim 4, and the compositions covered by claim 12, of the Gall '814 patent, in the mid-1980s, a person of ordinary skill in the art relevant to claim 4 would have possessed at least a Ph.D. degree in chemistry and, more particularly, organometallic, synthetic, or bio-organic chemistry, and additionally would have had training in the field of organophosphorus chemistry, either through post-doctoral training and experience or through industrial experience.

(Benedict Rpt., Waddell Decl., Exh. A, ¶ 63).

A different level of skill in the art would apply to claim 8 of the '814 patent, which relates to a method of treatment. Roche's expert, Charles H. Chesnut, III, M.D. has over forty years of medical experience and has extensive experience treating osteoporosis. (Chesnut Rpt., Waddell Decl. , Exh. C, ¶¶ 2-10). According to Dr. Chesnut:

> It is my opinion that, in 1986 (and, for example, as of July 11, 1986 which is the priority date of the '814 patent), a person of

> ordinary skill in the art to which the inventions of claim 8 of the Gall '814 patent pertains would have possessed an M.D. or Ph.D. in anatomy, physiology or pharmacology. Additional training in the form of residency or fellowship in internal medicine or obstetrics or gynecology, with a focus on endocrinology or other area related to metabolic bone diseases; or post-doctoral work or training in anatomy, physiology or pharmacology, with emphasis on skeletal anatomy, pathology, physiology and pharmacology. A person of ordinary skill in this area in 1986 would also have at least 1-3 years of practical experience in preclinical studies that included efficacy and toxicology studies using various models and techniques available at that time, or in clinical research relating to the treatment of metabolic bone diseases.

(Chesnut Rpt., Waddell Decl. , Exh. C, ¶ 21).

1. The Meaning of "1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid"

This disputed term appears in each of claims 4, 8, and 12 of the '814 Patent. With reference to the '814 Claim Chart (Waddell Decl., Exh. F, p. 1), Defendant Apotex proposed the following construction:

> Means 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-disphosphonic acid only, and does not include a salt thereof.

Roche instead proposed this construction:

> Means the compound 1-hydroxy- 3-(N-methyl-N-pentylamino)-propane-1,1-disphosphonic acid which is simply one of the possible ways of referring to ibandronic acid. Claim 4 does not exclude salt forms of ibandronic acid.

Roche's construction of the term "1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid" is that it is a chemical term that

would be understood by a person skilled in the art as meaning the compound which is today called "ibandronic acid." (See, Benedict Rpt., Waddell Decl., Exh. A, ¶¶ 50-55, 65 and the list of chemical synonyms attached to his opening expert report as Exhibit C; Chesnut '814 Rpt, Waddell Decl., Exh. C, ¶ 23).

Roche's position is that claim 4 does not exclude salt forms of ibandronic acid because claim 4 of the '814 patent explicitly reads[12]:

> 4. The diphosphonate compound of claim 1 designated 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid **and the physiologically active salt thereof.**

The phrase "and the physiologically active salt thereof" in claim 4 obviously modifies the phrase "The diphosphonate compound of claim 1 designated 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid" in claim 4. See, the discussion below concerning the meaning of this term.

2. The Meaning of "physiologically active salt"

This disputed term is used only in asserted claim 4 of the '814 patent. With reference to the '814 Claim Chart (Waddell Decl., Exh. F, p. 1), Defendant Apotex proposed the following construction:

> Means a salt of 1-hydroxy-3-(N-methyl- N-pentylamino)-propane- 1, 1-disphosphonic acid that is physiologically active.

[12] ('814 Patent, Col. 13, ll. 36-39, JOINT APP-0009)(Emphasis supplied).

Roche instead proposed this construction:

> Means a salt form of ibandronic acid that is physiologically active, i.e., capable of producing a physiological activity.
>
> The sodium salt of ibandronic acid, known as "ibandronate sodium," is an example of a physiologically active salt of ibandronic acid. See Opening Expert Report of James J. Benedict, Ph.D., July 28, 2009.

The '814 patent specification does not accord any specialized meaning to this term. A person skilled in the art would understand that the phrase "physiologically active salt thereof," means that the claimed salt form of ibandronic acid is a salt that is capable of producing the intended physiological (or medical) effect. (Benedict Rpt., Waddell Decl., Exh. A, ¶ 71). The "sodium" salt form is one of the "preferred" salt forms identified in the Gall '814 patent. ('814 patent, Col. 6, lines 4-11, JOINT APP-0005). Claim 4 simply includes a salt form of ibandronic acid that is capable of being absorbed and producing a physiological effect – e.g. ibandronate sodium. (Benedict Rpt., Waddell Decl., Exh. A, ¶¶ 73-74).

Defendants Apotex and Cobalt both served rebuttal expert reports concerning this issue on September 15, 2009, and presumably will rely on these in their initial claim construction brief(s). Roche's reply expert reports addressing this issue are due on October 15, 2009 and will be discussed in Roche's responsive claim construction brief due on December 4, 2009.

3. The Meaning of "administering … 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid"

This disputed wording appears only in claim 8 of the '814 patent. Claim 8 of the '814 patent reads[13]:

> 8. A method for the treatment or prophylaxis of calcium metabolism disturbance or disease comprising **administering** a pharmaceutically effective amount of at least one of the compounds designated 1-hydroxy-3-(N-methyl-N-nonylamino)-propane-1,1-diphosphonic acid, **1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid** and 1-hydroxy-3-(N-isobutyl-N-methylamino)-propane-1,1-diphosphonic acid.

With reference to the '814 Claim Chart (Waddell Decl., Exh. F, p. 3), Apotex and Roche do not differ as to the meaning of "administering", per se. The term "administering" has its ordinary meaning. The '814 patent specification states, "[t]he new compounds of general formula (I) according to the present invention and the salts thereof can be administered enterally or parenterally in liquid or solid form. For this purpose, there can be used all conventional forms of administration, for example tablets, capsules, dragees, syrups, solutions, suspensions and the like." ('814 Patent, Col. 6, lines 12-18, JOINT APP-0005).

Roche contends that the term "1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid" used in claim 8 means ibandronic acid. (Benedict

[13] ('814 Patent, Col. 14, ll. 11-18, JOINT APP-0009)(Emphasis supplied).

Rpt., Waddell Decl., Exh. A, ¶ 78) . See discussion of this term above. The dispute that has really emerged here is over what is administered when a drug product containing a sodium salt of ibandronic acid reaches a patient's stomach and dissolves.

Defendants Apotex and Cobalt both served rebuttal expert reports concerning this issue on September 15, 2009, and presumably will rely on these in their initial claim construction brief(s). Roche's reply expert reports addressing this issue are due on October 15, 2009 and will be discussed in Roche's responsive claim construction brief due on December 4, 2009.

4. The Meaning of "pharmaceutical composition… containing … in a pharmaceutically acceptable carrier … at least one compound designated ... 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid"

This disputed term only appears in claim 12 of the '814 patent. Claim 12 of the '814 patent reads[14]:

> 12. **A pharmaceutical composition** for the treatment or prophylaxis of calcium metabolism disturbance or disease **containing** an effective amount in a pharmaceutically acceptable carrier of at least one compound designated 1-hydroxy-3-(N-methyl-N-nonylamino)-propane-1,1-diphosphonic acid, **1-hydroxy-3-(N-methyl-N-pentylamino)-**

[14] ('814 Patent, Col. 14, ll. 32-41, JOINT APP-0009)(Emphasis supplied).

> **propane-1,1-diphosphonic acid**, and 1-hydroxy-3-(N-isobutyl-N-methylamino)-propane-1,1-diphosphonic acid.

With reference to the '814 Claim Chart (Waddell Decl., Exh. F, pp. 5-7), Apotex and Roche do not differ as to the meaning of "pharmaceutical composition… containing … in a pharmaceutically acceptable carrier ", per se. The phrase "pharmaceutical composition" is not assigned any special meaning in the specification. It is a phrase that is ubiquitous in United States patents, and it simply states what the invention is. (Benedict Rpt., Waddell Decl., Exh. A, ¶ 80). That construction therefore is simply how one would ordinarily understand the phrase.

The '814 patent lists several examples of carriers covered by the phrase "pharmaceutically acceptable carriers." They include liquid and solid carrier materials. ('814 Patent, column 6, lines 26–36, JOINT APP-0005). Accordingly, the phrase "pharmaceutically acceptable carrier," as recited in claim 12, should be construed as meaning the types of carriers identified in the specification of the Gall '814 patent. (Benedict Rpt., Waddell Decl., Exh. A, ¶ 81). That construction is simply how one skilled in the art would ordinarily understand the phrase.

The dispute that appears to be emerging here is as to the meaning in claim 12 of the term "at least one compound designated … 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid". Roche contends that this term

means that the claimed pharmaceutical composition contains at least one of the three compounds listed in the claims, one of which is ibandronic acid (i.e. "1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid"). (Benedict Rpt., Waddell Decl., Exh. A, ¶ 80) . See discussion of this term above. Since the accused infringing products would use a sodium salt of ibandronic acid, Roche is alleging infringement of this claim under the doctrine of equivalents.

Defendants Apotex and Cobalt both served rebuttal expert reports concerning this issue on September 15, 2009, and presumably will rely on these in their initial claim construction brief(s). Roche's reply expert reports addressing this issue are due on October 15, 2009 and will be discussed in Roche's responsive claim construction brief due on December 4, 2009.

5. The Meaning of "calcium metabolism disturbance or disease"

This term appears in the preambles of independent claims 8 and 12 of the '814 patent. The preamble of claim 8 of the '814 patent reads[15]:

> 8. A method **for the treatment or prophylaxis of calcium metabolism disturbance or disease** comprising administering …

The preamble of claim 12 of the '814 patent reads[16]:

[15] ('814 Patent, Col. 14, ll. 11-18, JOINT APP-0009)(Emphasis supplied).

[16] ('814 Patent, Col. 14, ll. 32-41, JOINT APP-0009)(Emphasis supplied).

> 12. A pharmaceutical composition **for the treatment or prophylaxis of calcium metabolism disturbance or disease** containing an effective amount ….

With reference to the '814 Claim Chart (Waddell Decl., Exh. F, pp. 3 and 6), Roche's construction of this term is based on the disclosure in the '814 Patent specification which states that the inventive compounds "can be used … for the broader treatment of calcium metabolism disturbances. In particular, they can be used where the bone formation and breakdown is disturbed, i.e. they can be used for the treatment of diseases of the skeletal system, for example **osteoporosis**." ('814 Patent, Col. 1, ll. 30-34, JOINT APP-0003)(emphasis added). Apotex' response to this had been:

> In light of Roche's proposed definition, Apotex does not believe that any dispute it might have with regard to Roche's proposed definition would be material to any issue in this case, and therefore it is not necessary for the Court to construe this term.

Roche's construction of this term as used in claim 8 ("[a] method for the treatment or prophylaxis of calcium metabolism disturbance or disease comprising …") is that the phrase "calcium metabolism disturbance or disease," states the purpose of the invention, which is to treat calcium metabolism disturbance or

disease, one of which is osteoporosis. (Benedict Rpt., Waddell Decl., Exh. A, ¶ 76; Chesnut '814 Rpt., Waddell Decl., Exh. C, ¶ 37.)

Roche's construction of this term as used in claim 12 ("[a]pharmaceutical composition for the treatment or prophylaxis of calcium metabolism disturbance or disease containing an effective amount …") is that the phrase "calcium metabolism disturbance or disease," again states the purpose of the invention, which is to treat a calcium metabolism disturbance or disease, one of which is osteoporosis. This provides the context for an "effective amount" of the drug recited in claim 12 (Benedict Rpt., Waddell Decl., Exh. A, ¶ 80).

C. The '938 Patent Terms

Again, claims are construed as they would be understood by the person skilled in the art. *Phillips v. AWH Corp* at 1314-16. Dr. Bilezikian described the art pertaining to the '938 patent as follows:

> When given orally, bisphosphonates may result in upper gastrointestinal tract side effects because they can irritate mucous membranes, *e.g.* through esophageal gastric disturbances. This is reflected in the Bauss patents. See Bauss '938 patent at col. 1, lines 57-67, see Bauss '957 patent at col. 1, lines 52-55. Bisphosphonates also have low oral bioavailability. Prior to Roche's once monthly oral BONIVA, the oral route of administering bisphosphonates had to follow inconvenient recommendations of use for the patient because they had to be taken on a more frequent basis (daily or weekly). Id.

(Bilezikian Rpt., Waddell Decl., Exh. B, ¶ 27). According to Dr. Bilezikian:

> Both of the Bauss patents claim an oral dosing regimen which was not known in 2000-2002. The method relates to administering a bisphosphonate, such as ibandronate, "once-monthly."….
>
> Prior to Roche's once-monthly dosing methods, the only oral administration methods approved in the United States for the treatment or prevention of osteoporosis which employed a bisphosphonate compound involved daily or weekly administrations.

(Bilezikian Rpt., Waddell Decl., Exh. B, ¶¶ 29 and 31). He described the level of skill in this art as follows:

> It is my opinion that between 2000-2002, a person of ordinary skill in the art to which the claimed methods of the Bauss '938 and '957 patents pertain would have possessed an M.D. or a Ph.D. in anatomy, physiology or pharmacology. Additional training in the form of residency or fellowship in internal medicine or obstetrics or gynecology, with a focus on endocrinology or other area related to metabolic bone diseases; or post-doctoral work or training in anatomy, physiology or pharmacology, with emphasis on skeletal anatomy, pathology, physiology and pharmacology. A person of ordinary skill in this area in 2002 would also have at least 1 - 3 years of practical experience in preclinical studies that included efficacy and toxicology studies using various models and techniques available at that time, or in clinical research relating to the treatment of metabolic bone diseases.

(Bilezikian Rpt., Waddell Decl., Exh. B, ¶ 20).

1. The Meaning of "commencing treatment by orally administering to a subject in need of such treatment a first dose, on a single day"

a. The Meaning of "commencing treatment"

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, pp. 4-5), Defendants (other than Cobalt) proposed the following construction:

> Means "beginning or starting the first time administration to a subject of a bisphosphonic acid or a pharmaceutically acceptable salt thereof for treating or inhibiting of osteoporosis". E.g., Prosecution History, December 11, 2006 Amendment.

Roche instead proposed this construction:

> Roche contends that the claim term "commencing treatment" refers to commencing the monthly dosing of ibandronic acid or a pharmaceutically acceptable salt thereof as recited in the claim, as opposed to the loading dose/maintenance dose regime described in the Schofield reference (U.S. Patent Application Publication No. 2003/0118634). See, the Prosecution History of USSN 10/998,849, also cited by Defendants, which contains applicants' arguments submitted December 11, 2006 (explaining that the claims were amended to exclude the administration of a "loading dose administered over 7 to 180 days, as required by Schofield to be efficacious…")

The parties all refer to the same intrinsic evidence, yet differ as to its proper interpretation. In construing the claims, the Court may look to the prosecution history. *Markman*, 52 F.3d at 967; *Sorenson v. International Trade Commission*, 427 F. 3d at 1378.

The disputed '938 patent claim terms all arose as the result of an amendment made during patent prosecution to overcome a rejection based on alleged obviousness over Schofield, et al., U.S. Pub. No. 2003/0118634 ("Schofield et al"). (JOINT APP-1259-1280). The amendment and associated remarks do not support Defendants' proposed construction.

By way of background, "Schofield discusses a dosing regimen requiring an initial bisphosphonate loading dose period of 7 to 180 days, followed by a maintenance period of enormous possible scope, both temporally (i.e., daily, twice weekly, weekly, bi-weekly, or monthly) and with respect to the dose (0.5 to 0.05 of the total loading dose)." (Dec. 11, 2006 Amdt., JOINT APP-1264). The applicants' attorney discussed various deficiencies of Schofield et al. and then argued the patentability of the amended claims, stating:

> Despite the deficiencies of Schofield, in order to advance prosecution applicants have amended the present claims **to exclude the possibility of employing a loading dose administered over 7 to 180 days, as required by the methods disclosed by Schofield to be efficacious.** Claims 24 to 28 and 30 to 39 exclude a loading dose by requiring the administration of a first dose, on a single day, of a pharmaceutical composition comprising from about 100 mg to about 150 mg bisphosphonic acid or an amount of a pharmaceutically acceptable salt hereof that is equivalent to from about 100 mg to about 150 mg of bisphophonic acid, followed by a monthly administration of the same. New claims 40 to 54 exclude the method of Schofield by employing "consisting of" transitional language. Thus, the present claims can not properly be said to encompass the maintenance dosing of Schofield.

> Nothing in Schofield provides any expectation that one could successfully treat or inhibit osteoporosis using a single day, monthly dosage regimen that begins with a single oral dose of about 100 to about 150 mg of bisphosphonic acid or a pharmaceutically acceptable salt thereof, as presently claimed. Indeed, the examples in Schofield never disclose using an oral maintenance dose any higher than those set forth as safe for Actonel (Tab 1) and Fosamax (Tab 2) prescribing information (35 mg/week and 70 mg/week, respectively). Accordingly, it is respectfully submitted that the grounds for the rejection should be withdrawn.

(Dec. 11, 2006 Amdt., JOINT APP-1265-66)(Emphasis added). Thus the purpose of the claim amendments was to exclude the different dosing regimen described in Schofield, et al. Read in this context, the term "commencing treatment" refers to the dosing regimen (once monthly) using the dose (150 mg of bisphosphonate) recited in the claim.

b. The Meaning of "orally administering to a subject in need of such treatment"

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, p. 5), Defendants proposed the following construction:

> Defendants (other than Cobalt): Means "the act of giving or taking by mouth to or by a human or mammal."
>
> Cobalt: Means the act of giving by Person A (i.e. the administrator) to person B (i.e. the subject in need of such treatment as defined below).

Roche proposed this construction:

> Roche agrees with Defendants (except Cobalt) that this claim term generally means "the act of giving or taking by mouth to or by a human or mammal."

> But, because the claim is directed to osteoporosis and the recited dose is about 150 mg of bisphosphonic acid, Roche contends that this claim would be understood by a person skilled in the art as limiting the method to oral administration to a human. Roche does not agree with Cobalt's alternate proposed definition.

All of the Defendants except for Cobalt are in agreement with Roche that the phrase "orally administering to a subject in need of such treatment" is readily understandable and does not require the Court to perform a claim construction analysis of that phrase. Cobalt, however, has contended that the phrase should be read to include limitations that are simply not present in claim 1 and which would improperly narrow claim 1. Roche believes that the ordinary meaning of the phrase is the proper construction.

The phrase "orally administering to a subject in need of such treatment" simply means "that a patient, such as a post-menopausal woman who needs to be treated, takes the composition by mouth." (Bilezikian Rpt., Waddell Decl., Exh. B, ¶ 45; Chesnut Rpt., Waddell Decl., Exh. D, ¶ 49). That is the ordinary meaning of each of those terms. As with the other claim phrases discussed above, nothing in claim 1, or in the Bauss '938 patent, or in its file history, requires that "orally administering to a subject in need of such treatment" be construed in a way that would limit it beyond its plain meaning.

c. The Meaning of "a first dose"

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, pp. 5-6), Defendants (other than Cobalt) proposed the following construction:

> Defendants (other than Cobalt): Means "an initial amount to be taken by the subject on beginning or starting treatment of osteoporosis." e.g., Prosecution History, December 11, 2006 Amendment. It may be a single dose or multiple subdoses. For example, if the dose is 150 mg, it may be taken as one (1) 150 mg dose, two (2) 75 mg sub-doses, or three (3) 50 mg sub-doses. Col. 4, lines 10-19. During prosecution, Roche disclaimed an initial bisphosphonate loading dose followed by a maintenance period. E.g., Prosecution History, December 11, 2006 Amendment.
>
> Cobalt: Means first dose of any drug in the treatment therapy. It excludes patients who previously received therapy.

Roche instead proposed this construction:

> Roche contends that the claim term "a first dose" was described in the cited Prosecution History as meaning that the dosage used in the claimed dosing regimen is the same every month and that the claims do not read on the administration of a "loading dose administered over 7 to 180 days, as required by Schofield to be efficacious…"

The phrase "a first dose, on a single day, of a solid pharmaceutical composition" simply means "that the patient takes a first dose of the solid composition (such as a tablet), in one day." (Bilezikian Rpt., Waddell Decl., Exh. B, ¶ 45; Chesnut Rpt., Waddell Decl., Exh. D, ¶ 49). That is the ordinary meaning of each of those terms. Cobalt's proposed construction appears to require that the

phrase be construed as covering the first dose of any drug, rather than the bisphosphonate required by the claim. However, the claim does not recite any drug; it recites a specific monthly dose of a bisphosphonate. Accordingly, the phrase "a first dose, on a single day, of a solid pharmaceutical composition" as recited in claim 1, should be construed as meaning that the patient takes "a first dose" of the solid composition (such as a tablet), in one day.

As noted above, the claims were amended during prosecution. The purpose of the claim amendment was to exclude the different dosing regimen described in Schofield, et al. (Dec. 11, 2006 Amdt., JOINT APP-1266). Read in this context, the term "a first dose, on a single day, of a solid pharmaceutical composition" refers to the dosing regimen (once monthly) starting with the dose (e.g., 150 mg of bisphosphonate) recited in the claim and not with a loading dose.

d. The Meaning of "on a single day"

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, p. 6), Defendants (other than Cobalt) proposed the following construction:

> Defendants (other than Teva): Means "during one twenty-four (24) hour period."
>
> Teva: Means "during a calendar day"

Roche instead proposed this construction:

> Roche does not agree with the Defendants' (except Teva) proposed definition. Roche agrees with Teva's proposed

> construction that the claim term "on a single day" means during a calendar day.

The '938 patent specifications uses the term "day" as follows: "The term 'one, two, or three consecutive days per month' means administration of one to three … tablets on one, two, or three consecutive days of the month, preferably on one day per month." ('938 Patent, Col. 3, lines 51-54, JOINT APP-0427). There is no mention here whatsoever of a "twenty-four hour period" as advanced by Defendants. The term "day" is obviously used to denote a calendar day.

e. The Meaning of "once monthly"

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, p. 10), Defendants (other than Cobalt) proposed the following construction:

> Exclusively one time only per month where "month" has the generally accepted meaning as a measure of time amounting to approximately four (4) weeks, approximately 30 days, or approximately 1/12 of a calendar year. ("month"). See Col. 3, lines 55-58).

Roche instead proposed this construction:

> Roche contends that the claim term "once monthly" means once during a calendar month.
>
> In response to Defendants proposed construction, Roche contends that a month is generally understood "as a measure of time amounting to approximately four (4) weeks, approximately 30 days, or approximately 1/12 of a calendar year," and that there are twelve such months in a year. In other

> words, if a patient followed the claimed dosing regimen for one year, she would take a total of twelve doses.

The '938 patent specification defines "month" "in accordance with its generally accepted meaning as a measure of time amounting to approximately four (4) weeks, approximately 30 days, or approximately 1/12 of a calendar year." ('938 patent, Col. 3, lines 55-58, JOINT APP-0427). This is the general understanding of what a calendar month is, as not all months are exactly the same length, but each is approximately 1/12 of a calendar year.

2. The Meaning of "continuing said treatment by orally administering, once monthly on a single day"

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, p. 9), Defendants (other than Cobalt) proposed the following construction:

> Defendants (other than Cobalt) "Treatment" refers to the treatment of osteoporosis.
>
> Cobalt: This term is indefinite.

Roche instead proposed this construction:

> Roche contends that the claim term "continuing said treatment," refers to the recited dosing regimen for the treatment of "osteoporosis." The applicants explained in the Prosecution History cited by Defendants that the claimed dosing regimen requires monthly administration of the same monthly dose, as distinguished from the loading dose/maintenance dose regimens described in Schofield.

As noted above, the claims were amended during prosecution. The purpose of the claim amendment was to exclude the different dosing regimen described in Schofield, et al. (Dec. 11, 2006 Amdt., JOINT APP-1266). Read in this context, the term "continuing said treatment by orally administering, once monthly on a single day" refers to the dosing regimen (once monthly) recited in the claim and excludes a regimen that includes a loading dose.

3. The Meaning of "consisting of orally administering to a subject in need of such treatment once monthly"

This limitation appears only in independent claim 16 of the '938 patent. Claim 16 of the '938 patent reads[17]:

> 16. A method for treating or inhibiting osteoporosis **consisting of orally administering to a subject in need of such treatment once monthly**, a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 100 mg to about 150 mg of said bisphosphonic acid.

With reference to the '938 Claim Chart (Waddell Decl., Exh. H, p. 11), Defendants (other than Cobalt) proposed the following construction:

> The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. MPEP 2111.03.

Roche instead proposed this construction:

[17] ('938 Patent, Col. 8, ll. 12-17, JOINT APP-0429)(Emphasis supplied).

> The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim, but would not exclude anything that is unrelated to the claimed invention. MPEP 2111.03.
>
> The applicants explained in the Prosecution History that this transitional phrase was directed to the dosing regimen and that it distinguishes the claimed monthly dosing regimen from the loading dose/maintenance dose regimen of Schofield. (same cite in "commencing treatment" definition in claim 11 above).

As noted above, the claims were amended during prosecution. The purpose of the claim amendment was to exclude the different dosing regimen described in Schofield, et al. (Dec. 11, 2006 Amdt., JOINT APP-1266). Read in this context, the term "consisting of orally administering to a subject in need of such treatment once monthly" refers to the dosing regimen (once monthly) recited in the claim and excludes a regimen that includes a loading dose. Id.

D. The '957 Patent Terms

The disputed terms in the '938 patent likewise appear in the independent claims of the '957 patent. Roche does not assert a different interpretation for these common terms used in both patents.

V. CONCLUSION

For all the foregoing reasons Roche respectfully requests that each of the disputed terms be construed as proposed by Roche herein.

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